

Healixia, 25/09/2020

From vision to reality

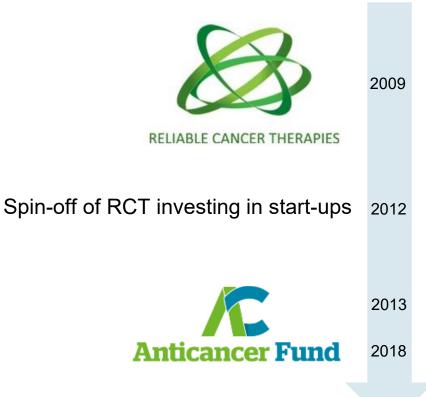
Investing in promising cancer treatments, putting patient needs first

Guy Buyens, Medical Director, Anticancer Fund Gabry Kuijten, Coordinating physician My Cancer Navigator

Who we are





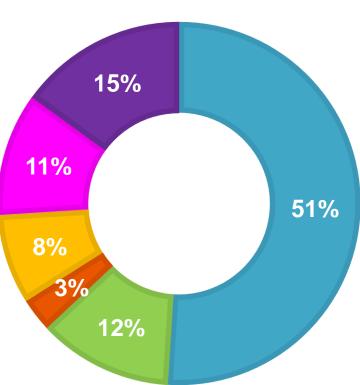


- Swiss non-profit organisation
- Founded by entrepreneur Luc Verelst
 - Started by Lydie Meheus (CEO)



- Belgian private research foundation
 - Belgian foundation of public utility





The ACF 2019 = € 1,9 M

- All overhead costs paid by the founder
- Donations are used entirely to fund the projects

research

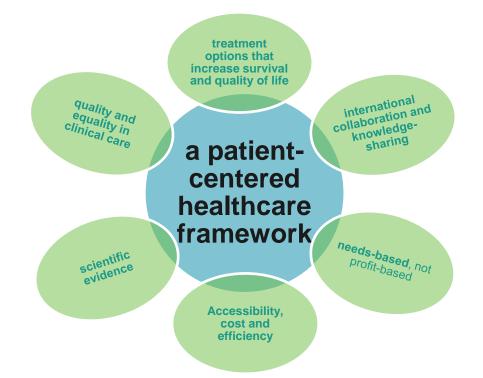
- patient information
- policy
- fundraising and branding
- operating costs
- knowledge building

" Private philanthropy has the freedom to think different, to do different and to make a difference"



Our vision

Every cancer patient has the right to a chance in their fight against the disease.



- 1. Informing patients
- 2. Involvement in clinical trials
- 3. Acting for policy changes

Involvement in clinical trials





Involvement in clinical trials

Clinical research is our core activity:

- We are an independent, non-profit intermediary working with universities, hospitals and other stakeholders to set up **investigator-driven clinical trials**.
- Our trials focus on therapy avenues with **limited commercial value** for the pharma industry but potential societal value.
- As an impact-driven organisation, we select trials that can **bring new treatment options to patients** as rapidly as possible.









Protocol development and documentation



Criteria to get funding by the ACF

- 1. Patient-centered
- 2. Industry is not interested
- 3. Improving survival or cure rate
- 4. Limited risk of trial execution failure
- 5. Low competition





Evaluation Process



Projects selected through:

- Spontaneous applications (incl. some scouting)
- Call for projects



Our trial portfolio

> 11 trials completed (published or manuscript in writing)

- > 10 trials ongoing (open or in follow-up)
- > 4 trials in preparation



Focus area:

- Drug repurposing
- Less common and rare cancers
- Combination therapies
- Preventing tumour recurrence

Scientifically promising treatments that have the potential for significant positive impact but lack a market push for further research

ViDME PROSPER PropAngio Neoadiuvant ß-blocker in Vitamin D treatment for Perioperative use of a Bangiosarcoma patients blocker and an antimelanoma inflammatory drug in pancreatic cancer PIONEER **B-AHEAD-3** METRO PD-1 Pre-operative hormone Immunotherapy Diet and exercise for combined with low-dose treatment for ER+ breast breast cancer patients chemotherapy in cancer patients paediatric cancer **ASPIRIN** METZOLIMOS PRIMMO Immunotherapy, radiation Advanced bone cancer Aspirin for recurrence treatment with a and survival in colon and an immune combination of modulatory combination cancer chemotherapy and in cervical and uterine immunosuppressants cancer AML-ViVA 10 recruiting and ongoing trials

Treating leukaemia patients with chemotherapy and 2 repurposed drugs

11



2019: Request for Application

Reducing recurrence rate for cancer patients treated with curative intent.

- Selected trial: pan-European **study in retroperitoneal sarcoma** (250 patients to be recruited over 5.5 years): EORTC STRASS II-trial
- Total study cost of approximatively €2.9M, of which €1.4M was already secured. The Anticancer Fund agreed to provide €700,000.

		Articles
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- The STRASS-2 trial is the logical next step after the STRASS trial.
- Final results of STRASS have just been published in the Lancet Oncology. STRASS was able to show that:
 - > preoperative radiotherapy is not needed in patients with resectable retroperitoneal sarcoma. A major results for patients who will now be spared an unnecessary treatment and its associated toxicity.
 - > running a definitive trial on a major clinical question in a rare sarcoma is possible thanks to collaboration
- With STRASS-2 we hope to show that neoadjuvant chemotherapy is worth it, as it may improve survival of patients with retroperitoneal sarcomas.

2020: Joint Call for Research Proposals



Applicants are strongly encouraged to include patient input into clinical trial design and priority will be given to those applications that clearly demonstrate this input

Amount available for this call for proposals will be at least US\$ 3 million. The amount allocated per grant will depend on the number of proposals selected for funding.

Application Deadline: February 28, 2020

Research proposals must be submitted through proposalCENTRAL at the link: https://proposalcentral.com/ProposalCl.asp?SectionID=76398ProposalID=-1 The winning proposals will be announced in the 3* quarter of 2020.



- Call for Research proposals
- Together with "Rising Tide Foundation for Clinical Cancer Research", a Swiss-based nonprofit organization
- Amount available for this call for proposals: at least US\$ 3 million
- Application deadline was 28 February 2020
- Final projects (2) selected, contract discussions ongoing

Example of focus area: Repurposing

REDO DB The Repurposing Drugs in Oncology Database

Anticancer Fun

Drug repurposing is a drug development strategy predicated on the rouse of existing loansed drugs for new modical indications. Based on extensive literature research, the ReDO project has identified 25% Sociesid nous-chance drugs with published evidence of anticancer acable.



- Drug development strategy predicated on the reuse of existing licensed drugs for new medical indications
- A cost-efficient way to increase cancer patients' treatment options.
- Repurposing still faces important scientific, financial and regulatory hurdles.

At the Anticancer Fund:

- Investing in clinical trials
- ReDO database
- Connecting stakeholders and policy work

Acting for policy changes





Example of policy work

Bringing off-label indication on-label

Work within the EU Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP)

Off-label vs. on-label

- Off-label, though possible, comes with problems (delays, reimbursement, heterogeneity between EU countries)
- One issue is the lack of incentives for companies to bring an off-label indication onlabel, in particular for inexpensive and/or generic drugs.
- Topic of interest for the EU Commission Expert Group STAMP

Connecting stakeholders





Paediatric platform

- In 2018 there was a lot of media attention regarding **DIPG treatment in Mexico**.
- **RIZIV/INAMI** was contacted to support the treatment offered by the Clinic in Monterey, Mexico.
- Organisations like **KOTK**, **KickCancer**, the **Anticancer Fund (ACF**) and the **BSPHO** were solicited and a meeting was organised by Jo De Cock (INAMI/RIZIV).
- It was suggested to set up a platform to discuss how to better "support" patients and parents.
- A small **working group** (BSPHO, KickCancer, ACF) was created to explore the feasibility of a platform and to make recommendations.



Round table on cell therapy

- Joint exercise between 3 non-profit organisations active in Oncology and academic research laboratories active in the field of cell therapy in oncology
- Aim: ensure that academic projects can lead to **effective** treatments that could be brought to patients **in time**, in a **safe** and **affordable** way
- Round tables to address feasibility of academically developed cell therapy in Belgium:
 - March 2020: representatives of Belgian academic centres involved in cell therapy research in oncology
 - October 2020: CEOs of University hospitals and Tech Transfer people of Universities







Informing Patients





Informing patients

- In the past: ESMO guidelines for patients
- ReDo database
- Boek "100 vragen over kanker" with Johan Swinnen and KOTK (foreseen October 2020)
- Paediatric platform
- And...

My Cancer Navigator



My Cancer Navigator









- Patients sometimes have difficulty asking and/or understanding the information they need
- Cancer patients have many information needs, not all of which can always be adequately addressed during a visit
- Underlying reasons for suboptimal communication may be present both on the side of the patient as well as the healthcare provider
- There is a lot of disinformation online and offline

Goal: to support patients to engage in shared decision making, based on adequate and relevant information

Note: service is also available to physicians!

Henselmans et al. Health Expectations, 18, pp.2375–2388 Chua et al. ecancer 2018, 12:873 https://doi.org/10.3332/ecancer.2018.873

More information on: https://www.anticancerfund.org/en/informing-patients



— What we do

We provide non-judgmental, evidence-based information about

- specific types of cancer and their characteristics,
- treatment options suggested by international guidelines,
- experimental treatments and clinical trials,
- treatment centres and experts across borders,
- and drug interactions.

We also summarize the available scientific evidence on alternative or complementary treatments the patient is considering.



Who we are

ACF medical doctors:

- Gabry Kuijten Coordinating Physician MCN*
- Guy Buyens Medical Director
- Muriel Sterckx Physician MCN*

ACF scientists:

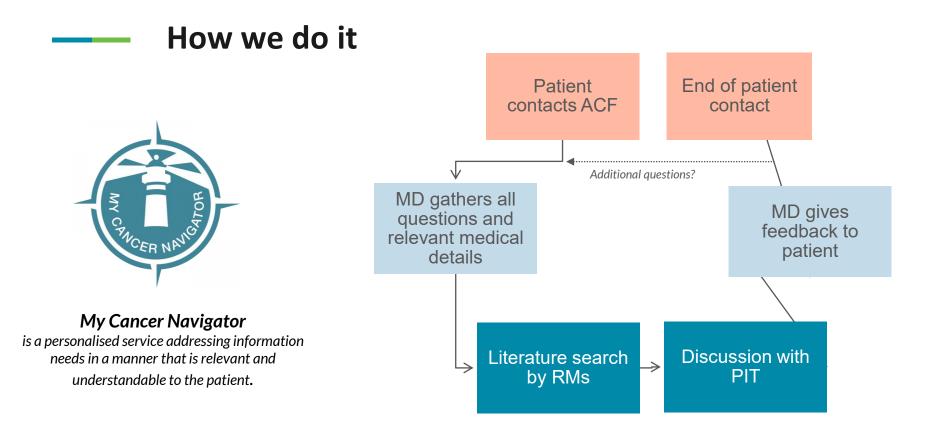
- Klara Rombauts Research Manager
- Liese Vandeborne Research Manager
- Rica Capistrano Research Manager

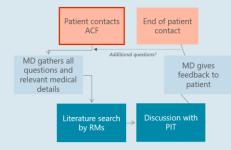
Consulting specialists:

- David Walker Medical Consultant (Paed CNS)
- Nicolò Battisti Medical Consultant (Onco)
- Nina Neuendorff Medical Consultant (Haemato)
- Sergio Crispino Scientific Consultant (Onco)



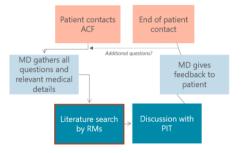






Patient contacts ACF

- Via phone, website contact form or e-mail
- Incoming cases are divided between MDs (contact with patient) and RMs (lit. search)
- E-mails are answered ASAP, usually on the same day or after 1 working day
- First call = who we are, what we do and how we work + which information about the patient we need + consent to privacy policy



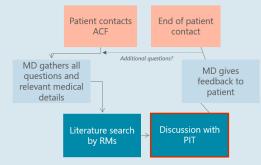
Literature search

- RMs perform a literature search to gather information for answering the patient's questions
- Frequently consulted sources: NCCN / ESMO guidelines PubMed / BioMedTracker / UpToDate ct.gov / ICTRP cam-cancer / MSKCC ExpertScape



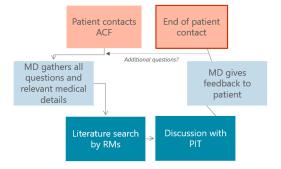


- <u>Template</u>
- Sample case



Discussion with PIT

- PIT meeting every Monday at 13h30
- RMs prepare and send out agenda in advance
- RMs take notes of discussions during PIT meeting
- MD and/or RM provides this feedback to patients (orally/written) after PIT meeting



End of contact

- If new questions arise, RM performs new search
- If all questions are answered, the contact ends

Disclaimer

"Please note that we do not provide advice nor a second opinion. We are a team of scientists and doctors. We encourage you to discuss our information with the treating physician."



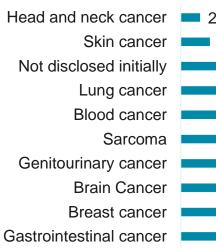


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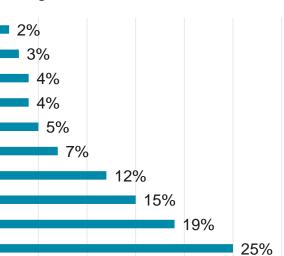


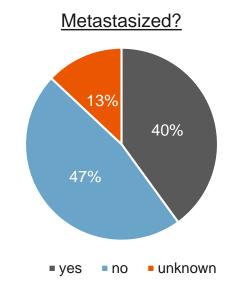


298 patient cases in 2019

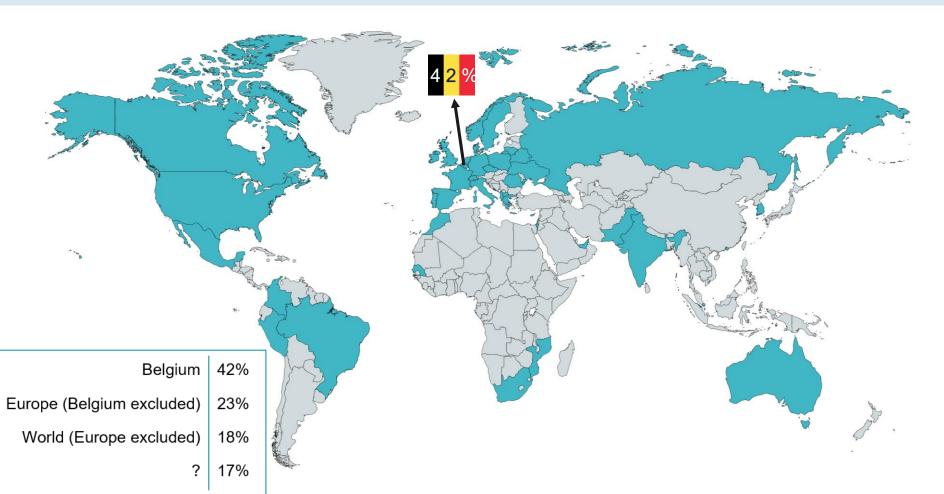








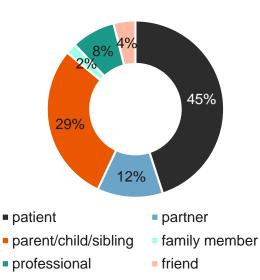




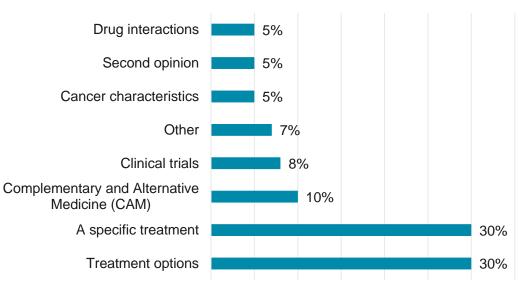


298 patient cases in 2019

Who is contact person?

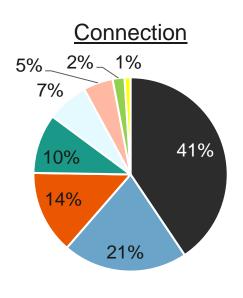


Questions about...









unknown

- via ReDO
- via partner

viaviavia medical professional

via press

onal • via organic internet search

via ACF-team

What's next for My Cancer Navigator?





— What's next

- Expand service to reach more patients *and* physicians
- Secure funding and/or collaborations to achieve a sustainable model
- Build or find a platform (CRM-like) to increase efficiency

ACF and pharma companies





Where does our work intersect?

Clinical trials

- Development and support e.g. investigational product, IIS requests
- Patient eligibility, recruitment status, expected results

Medical Information

- Referral of patients / physicians who might benefit from My Cancer Navigator
- Availability of medications e.g. expected reimbursement, expanded access etc